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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/443,863	11/19/1999	INDU PARIKH	401930/SKYEPHARMA	7862

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EXAMINER	
KISHORE, GOLLAMUDI S	
ART UNIT	PAPER NUMBER
1612	
MAIL DATE	DELIVERY MODE
01/14/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/443,863	PARIKH ET AL.	
	Examiner	Art Unit	
	Gollamudi S. Kishore, Ph.D	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *50-52,54,56-75,77,79-95,97-104 and 108-131* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *50-52, 54, 56-75, 77, 79-95, 97-104 and 108-131* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The RCE dated 10-30-07 is acknowledged.

Claims included in the prosecution are 50-52, 54, 56-75, 77, 79-95, 97-104 and 108-131.

Claim Rejections - 35 USC ' 103

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 50-52, 54, 56-75, 77, 79-95, 97-104 and 108-131 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/07414 (on record) in view of either Green (5,976,577) of record or Venkatesh (6,475,510).

WO discloses the same process of preparation for the rapidly dispersing oral dosage forms of hydrophobic compounds wherein the particles are coated with at least two surfactants; one of the surfactants is a phospholipid (surface modifying agent). The average particle sizes of the hydrophobic compound are less than 10 microns. The composition contains other claimed materials such as celluloses and mannitol. The process of preparation involves the mixing of the components (water insoluble active agent and the surface modifying agents) in an aqueous medium, sonicating it and lyophilizing the composition to form particles (note the abstract, page 2, line 25 through page 8, line 19, Examples and claims). WO further teaches that the lyophilized powders can be converted into granules or tablets with the addition of binders and other

excipients known in the art of tablet making (page 4, lines 14-17). What is lacking in the process of WO is the additional step of adding rapidly dispersible matrix-forming releasing agents to prepare rapidly disintegrating solid dosage form.

Green (5,976,577) discloses fast dispersing solid dosage forms of various drugs. The particles in Green are coated with polymers and lipid materials such as fatty acids (surfactants) and phospholipids. According to Green, the carrier material, which aids the rapidly disintegrating network, includes microcrystalline cellulose, mannitol, sorbitol and gelatin (abstract, col. 3, lines 43-60, col. 5, lines 30-48, col. 8, lines 20-31, Examples and claims, claim 12 in particular).

Venkatesh similarly discloses fast dispersing solid dosage forms of various drugs. The particles are coated with phospholipids in Venkatesh. According to Venkatesh, the carrier material includes mannitol, sorbitol and xylitol (abstract, col. 5, lines 8-39, col. 6, lines 9-35, col. 7, lines 39-67 and examples).

To add the step of the addition of bulking and releasing agents such as mannitol, microcrystalline cellulose and sorbitol in the method of preparation of WO, if the desired goal is to make the tablets of WO as rapidly disintegrating tablets, would have been obvious to one of ordinary skill in the art at the time the invention was made since the references of Green and Venkatesh each teach that these agents would enable the tables to disintegrate rapidly.

Applicant's arguments have been fully considered, but are not persuasive. Applicant argues that the present invention is directed to an improvement in the dispersibility of micronized particles through the specific selection of excipients and the

micronized particles as disclosed in WO 98/07414 are required in the practice of the present invention. Applicant further argues that the invention disclosed by WO 98 is a process of making non-aggregating submicron sized primary microparticles and the particles so produced. According to applicant, WO is concerned with suspensions and all of the exemplified formulations are suspensions in aqueous media. Further according to applicant, whereas WO 98 ***does suggest*** that the suspensions can be dried and formed into capsules or tablets, nothing is mentioned regarding the properties of these capsules when exposed to aqueous media. Applicant also argues that rapid disintegration time was not taught or even suggested by WO 98 and that there is no teaching that at least two, rapidly dispersible, matrix forming agents are mixed with the micro particles. Applicant further argues that neither adding a rapidly dispersible matrix-forming agent nor a disintegrating time of less than 2 minutes is taught or suggested by WO 98. These arguments have been extensively addressed by the examiner before. The examiner points out in addition that rapidly disintegrating solid dosage form without reciting the argued time units do not define a claim since the term 'rapidly' is a relative term. Furthermore, as pointed before, the motivation to add the additional steps to prepare rapidly disintegrating forms, if such forms are desired, could be derived from the secondary references. Applicant's arguments that Venkatesh does not teach or suggest the preparation of an aqueous solution but rather teaches blending intra-granular components which form a dry granulation mixture are not persuasive since irrespective of the method of preparation, Venkatesh teaches the same components which enable the composition to disintegrate rapidly. Applicant's arguments with regard

to lack of teachings of sizes in Venkatesh or Green are not persuasive since instant claims do not recite any sizes. The examiner also points out that WO indeed on page 4, lines 14-17 teaches that the particles of the invention may be lyophilized into powders which can be re-suspended or filled into capsules or converted into granules or tablets with the addition of binders and other excipients known in the art of tablet making. Therefore, it is within the skill of the art to add the excipients to the particles of WO in order to obtain a rapidly disintegrating preparation based on the teachings of the secondary references.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 50-52, 54, 56-75, 77, 79-95, 97-104 and 108-131 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable

over claims 1-11 of U.S. Patent No. 5,922,355 in combination with either Green (5,976,577) or Venkatesh (6,475,510). Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons. Claims in the said patent are drawn to a process of preparing microparticles of water insoluble drugs mixing the drug, a phospholipid and another surfactant and applying energy to reduce the particle sizes. Claims in instant application recite the same steps with further inclusion of a step of adding bulking /releasing agents to prepare rapidly disintegrating solid preparations. What is lacking in the patented claims reciting 'comprising the steps of' is the addition of bulking/releasing agents to prepare rapidly disintegrating solid dosage forms.

Green (5,976,577) discloses fast dispersing solid dosage forms of various drugs. The particles in Green are coated with polymers and lipid materials such as fatty acids (surfactants) and phospholipids. According to Green, the carrier material, which aids the rapidly disintegrating network, includes microcrystalline cellulose, mannitol, sorbitol and gelatin (abstract, col. 3, lines 43-60, col. 5, lines 30-48, col. 8, lines 20-31, Examples and claims, claim 12 in particular).

Venkatesh similarly discloses fast dispersing solid dosage forms of various drugs. The particles are coated with phospholipids in Venkatesh. According to Venkatesh, the carrier material includes mannitol, sorbitol and xylitol (abstract, col. 5, lines 8-39, col. 6, lines 9-35, col. 7, lines 39-67 and examples).

To add the step of the addition of bulking and releasing agents such as mannitol, microcrystalline cellulose and sorbitol in the method of preparation of 5,922,355, if the

desired goal is to make rapidly disintegrating tablets, would have been obvious to one of ordinary skill in the art at the time the invention was made since the references of Green and Venkatesh each teach that these agents would enable the tables to disintegrate rapidly. Instant fenofibrate is deemed to be anticipated by the patented claims, which recite generic water insoluble drug.

5. Claims 50-52, 54, 56-75, 77, 79-95, 97-104 and 108-131 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2, 4-25, 45-47, 52-53, 55-56, 65 and 101-119 of copending Application No. 10/260,788 in combination with either Green (5,976,577) or Venkatesh (6,475,510). Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons. Claims in the said copending application are drawn to a process of preparing microparticles of water insoluble drugs mixing the drug, a phospholipid and another surfactant and applying energy to reduce the particle sizes. Claims in instant application recite the same steps with further inclusion of a step of adding bulking /releasing agents to prepare rapidly disintegrating solid preparations. What is lacking in the claims of the copending application reciting 'comprising the steps of' is the addition of bulking/releasing agents to prepare rapidly disintegrating solid dosage forms.

Green (5,976,577) discloses fast dispersing solid dosage forms of various drugs. The particles in Green are coated with polymers and lipid materials such as fatty acids (surfactants) and phospholipids. According to Green, the carrier material, which aids the rapidly disintegrating network, includes microcrystalline cellulose, mannitol, sorbitol and

gelatin (abstract, col. 3, lines 43-60, col. 5, lines 30-48, col. 8, lines 20-31, Examples and claims, claim 12 in particular).

Venkatesh similarly discloses fast dispersing solid dosage forms of various drugs. The particles are coated with phospholipids in Venkatesh. According to Venkatesh, the carrier material includes mannitol, sorbitol and xylitol (abstract, col. 5, lines 8-39, col. 6, lines 9-35, col. 7, lines 39-67 and examples).

To add the step of the addition of bulking and releasing agents such as mannitol, microcrystalline cellulose and sorbitol in the method of preparation in the claims of said copending application, if the desired goal is to make rapidly disintegrating tablets, would have been obvious to one of ordinary skill in the art at the time the invention was made since the references of Green and Venkatesh each teach that these agents would enable the tables to disintegrate rapidly. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the copending application are drawn to the same process of preparation and the products resulting from said process and the process is directed to water insoluble drugs. 'Insoluble drugs' in said copending application anticipate instant species of water insoluble drug, fenofibrate.

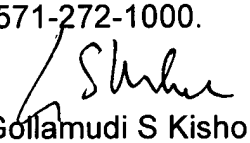
This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant indicates postponing the filing of the terminal disclaimer until the claims have otherwise reached allowance. The rejections are maintained.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S. Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Woodward Michael can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Gollamudi S Kishore, Ph.D
Primary Examiner
Art Unit 1615

GSK